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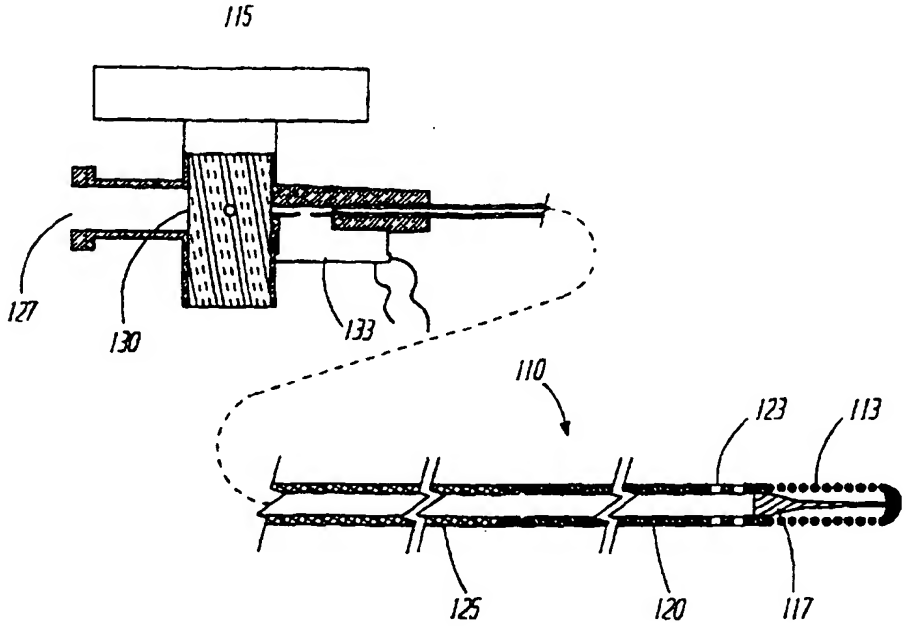

(57) Abstract

A guide wire (5) that is capable of sensing the phasic pressure of the distal end of the guide wire. The guide wire (5) has a central lumen (11) which provides a non-compliant fluid path from the distal end of the guide wire to a pressure transducer (30) at the proximal end of the guide wire.

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Pressure sensing guide wire

Background of the Invention

Pressure measurements made before, after, or during a therapeutic or diagnostic procedure can be important methods of analyzing any body conduit. In blood vessels, pressure measurement may be used to continuously monitor a patient's condition, to determine the patency of a specific artery or vessel, to assess the severity of a lesion or stenosis, or to asses the results of a therapeutic procedure such as angioplasty, atherectomy, or stenting. Pressure measurements may be of two types, phasic or flat line where the flat line pressure is the average of pressure changes over time.

One known device measures the pressure as a function of the deflection of a diaphragm located at the distal end of the catheter. While providing the ability to measure both phasic and flat line pressure, positioning the sensing part of the sensing device at the distal end of the catheter requires the sensing device to be made extremely small. Otherwise, the sensing device will impede blood flow and effect the pressure reading. In addition, catheters with the sensing device at the distal end do not allow for reuse of the expensive sensing device.

Another known device, called a fluid filled catheter-manometer, connects a sensing device to the proximal end of the catheter. A catheter-manometer uses a fluid column that can communicate pressure changes at the distal end of the device to a transducer located at the proximal end of the device. A catheter-manometer has the

advantage of having a reusable sensor and is therefore less expensive. Unfortunately, catheter-manometers have heretofore not been accurate at physiologic frequencies or able to provide a phasic pressure signal. The required bandwidth, or flat frequency response, for accurate physiologic pressure measurement in the heart about 30 hertz. Large catheter-manometers (8 Fr) are typically only 20 hertz and small catheter-manometers, like guidewire systems (.014"), may be less than 1 hertz. Further the bandwidth of catheter tip pressure devices may be several kilohertz. Clearly, prior art catheter-manometer systems have not had the required bandwidth or frequency response for accurate physiologic or phasic pressure measurement.

There are several factors causing prior art catheter-manometer systems to not have the required bandwidth or frequency response for accurate physiologic pressure measurement. One factor is that a relatively large amount of fluid mass must be moved with a relatively small amount of pressure. The movement of the mass is described by Newton's second law of motion: $F=Ma$, where the force F is a combination of a displacing force and restoring force. The displacing force is the pressure input and the restoring force is the natural rebound response of the system. Therefore, the density of the fluid becomes a contributing factor to the frequency response.

Another factor is resistance R. The resistance to flow in a catheter can be described by Poiseuille's equation: $R=8\mu L/\pi r^4$, where r is the internal diameter and L the length of the catheter. In a fluid-filled manometer system the fluid is typically not flowing, but rather is oscillating, as originally described by Lambossy (1952). Thus,

in a fluid filled manometer, the damping (resistance) varies as the square-root of the length and inversely as the cube of the radius as follows: $\beta = \frac{4\mu}{r^3}\sqrt{(\frac{pL}{\Delta E})}$.

Yet another factor is the elasticity or compliance C of the system. The catheter combined with the pressure transducer form an elastic volume in which the response is described by: $C = \frac{\Delta P}{\Delta C}$. Thus, the natural frequency response of the fluid filled catheter manometer will be determined by stiffness or compliance of all components in the system. Prior art systems are composed of the catheter, a manifold, tubing, fittings, and a transducer. Catheters are made of combinations of metals and plastics which may, depending on construction, have compliance which absorbs some of the pressure change. Manifolds are made of hard plastics which typically do not elastically deform. However, the tubing used is elastomeric, as are the gaskets used with the fittings. These elastomers are very flexible and will dampen pressure change in the fluid passing through them as described above.

Finally, the responsiveness of the pressure transducer within the sensing device is also a factor. As previously described, all components in the system contribute to the compliance C, and thus the frequency response. In order to have adequate sensitivity in the physiologic pressure range (about 0-5 Psi), blood pressure transducers have traditionally been designed for full scale signal output (maximum pressure rating) at applied pressures of 300 mmHg or 5 Psi. The very flexible diaphragms used to create adequate low pressure sensitivity increases the compliance of the system, and thus, lowers the frequency response. All of these factors have thus far contributed to making devices of this type less accurate in reproducing the exact

physiologic signals and produce pressure readings which are, in some devices, only an average of a patient's blood pressure over time.

The phasic pressure is a wave form. While the average pressure is of interest, physicians can readily identify a true physiologic wave form, with frequency content from DC up to about 30 Hz, and compare it to expected norms, thereby making phasic pressure measurement a highly valuable diagnostic tool.

Percutaneous coronary angioplasty is a specific procedure in which pressure measurement may be a valuable tool for lesion assessment and therapy assessment. The catheter which is used to measure pressure must be small enough so that the catheter itself does not interfere with measurement. In the epicardial coronary arteries, this requires catheters which are a fraction of a millimeter in diameter. It is also preferred to make the pressure measurement from a catheter which is already being used in a procedure, rather than exchanging for a pressure measuring catheter.

Prior art devices disclosed by Hastings, et al. in US Patent 5,450,853, Wise, et al. in US Patent 5,113,868, and Little in US Patent 5,313,957 have integrated micro-sensors into the distal end of a guide wire with an electrical or optical interconnect extending to the proximal end of the wire (approximately 1.8 meters). Since the wire is only 0.014 inches in outer diameter, it is very difficult to integrate the sensor and interconnect into the guide wire without altering the mechanical performance of the wire. The wire must torque, push, and steer sufficiently well to navigate the tortuous coronary vasculature. Wires with integrated distal sensors which accomplish this feat are inherently expensive to produce.

Prior art fluid lines which provide a phasic pressure signal are typically under-damped and have a diameter much larger than a guide wire. As an example, Model PXMK099 from the Edwards Critical Care division of Baxter Health Care in Irvine, CA consists of a pressure transducer with a six inch connecting pressure tube connected to a user supplied fluid filled tube. When the Baxter system is connected to a 0.014 inch hollow guide wire, the output signal is totally damped and only a flat line average pressure is displayed. This damping is due to the relatively high compliance of the Baxter system and the relatively large volume of water contained therein. To determine the minimum tube diameter which can transmit a phasic blood pressure signal through the Baxter system, 1.8 m long polyimide tubes of varying diameters ranging from 0.012-0.057 inches were connected via a Touey-Borst style connector to the Baxter system. Experiments on this system found an average system compliance of $\frac{dv}{dp} = 4\text{x}10^{-14}\ m^5/_{NT}$ $(m^3/Nt/m^2)$ and that the natural frequency was greater than or equal to 30 Hz in lines with diameters greater than 0.053" (0.0013 m). The lines with diameters less than 0.020 inches were over-damped and the lines with diameters larger than 0.020 inches were under-damped. Clearly prior art fluid lines which provide adequate frequency response are much larger than guide wires and still are not critically damped.

Another prior art device is disclosed by Tremulis in US Patent 4,953,553. Tremulis discloses a small diameter fluid filled line which can be used as a guide wire. However, blood pressure signals from this device may be extremely damped, giving only an average pressure value.

Therefore, it would be advantageous to provide a medical pressure sensing device with the reduced cost attributes of a fluid line, a small enough diameter to be used as a guide wire or to be used in small vessels, and sufficiently responsive to provide a phasic pressure signal.

Summary of the Invention

The present invention overcomes the deficiencies of the prior art by providing a medical pressure sensing device which may be used as a guide wire, is inexpensive, and responsive enough to measure a phasic pressure signal. A first embodiment of the invention has a tube with an interior diameter of less than 0.0013 m. A pressure transducer is connected to the tube and is in fluid communication with the interior of the tube. Fluid pressure changes at the distal end of the tube are communicated to the pressure transducer at the proximal end of the tube. The system compliance is sufficiently low to measure a phasic signal. In particular the system compliance $C < \left(\frac{D}{4f_0}\right)^2 x \frac{1}{\pi\rho}$ and $C < \left(\frac{\xi D^3}{32\eta}\right)^2 x \frac{\pi\rho}{L}$, where the interior diameter D is less than 0.0013 meters, L is the length of the tube, ρ is the density of the fluid, η is the viscosity of the fluid, f_0 is the natural frequency of the system, and ξ is the damping coefficient of the system.

Another embodiment of the medical pressure sensing device is a tube which is about 1-4 meter long and has an inner diameter of less than about 0.0013 m. There is less than about 1 cc of fluid within the tube which transfers pressure changes from the distal end of the tube to a proximal pressure proximal pressure transducer. The total

compliance of the system is less than about $4x10^{-14}\ m^5/Nt$. There may also be less than 0.004 cc of air trapped within the tube and the transducer.

The connector described in the previous embodiments may be a separate piece which may be connected to a medical fluid line. Examples of medical fluid lines include guide wires, catheters, needles, etc. The connector may further include a flush port and a stop cock. The total compliance of the connector and the pressure transducer may be less than $4x10^{-14}\ m^5/Nt$.

Alternatively, the pressure transducer may be a light source aligned to direct light through the pressure sensing device coupled with a photodetector which is aligned to detect light directed through the fluid line. The light source may be a laser diode and it may be infrared light.

In use, the embodiments of the medical pressure sensing device described above may be inserted into a vessel and advanced to a position where the pressure is desired to be measured. The phasic pressure may then be measured or an average may be computed to provide a pressure measurement. A catheter may then be advanced over the medical pressure sensing device and therapeutic procedures may be conducted. The phasic pressure can be monitored during therapeutic procedures or before and after to determine efficacy of the procedures. The pressure sensing device may also be moved within the vessel to determine the change in pressure measurement across a specific section of the body lumen.

Brief Description of the Drawings

Figure 1a is a side view of a first embodiment of the invention.

Figure 1b is a side view of a membrane covering a hole in the device in Figure 1a.

Figure 1c is a cross section of a second type of membrane covering a hole in the device in Figure 1a.

Figure 2a is a cross section of a another embodiment of the distal end of the device in Figure 1a.

Figure 2b is a cross section of a first variation of the embodiment shown in Figure 2a.

Figure 2c is a cross section of a second variation of the embodiment shown in Figure 2a.

Figure 2d is a cross section of third variation of the embodiment shown in Figure 2a.

Figure 3a is a side view of an embodiment of the connector assembly for use with the invention.

Figure 3b is an end view of the embodiment of Figure 3a.

Figure 3c is a cross section of another embodiment of a connector assembly for use with the invention.

Figure 4a is a cross section of another embodiment of the invention.

Figure 5 depicts a cross section of an alternative embodiment of the invention.

Figure 6 depicts a cross section of an alternative embodiment of the invention.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which like elements in different drawing are numbered identically. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention.

Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements. All other elements employ that which is known to those skilled in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that may also be used.

A coronary guide wire is an ideal device for measuring pressure. It is the first catheter placed into the artery, and the last to be removed. In addition, since coronary guide wires are typically 0.014 inches in diameter, they are also sufficiently smaller than the arteries being treated. Unfortunately, prior art devices described above are too expensive or do not provide adequate signal fidelity. For this reason it is desirable to have a high fidelity fluid line connecting the distal and proximal ends of a guide wire, with a pressure sensor located outside the body where there is ample space to determine pressures at lower cost.

Fluid filled lines have been thoroughly studied and modeled in the past. A fluid line and pressure transducer system are modeled as a simple harmonic oscillator with the mass of fluid in the line, fluid resistance provided by the viscosity of the fluid assuming laminar flow, and restoring force provided by the system compliance. The frequency response of the pressure transducer is then given as a fraction of its dc value by the expression $\frac{A}{A_0} = \frac{1}{\sqrt{[(f/f_0)^2 - 1]^2 + 4\xi(f/f_0)^2}}$. The natural frequency f_0 can be expressed by the equation $f_0 = \frac{D}{4}\sqrt{\frac{1}{\pi C \rho}}$. The total system compliance C equals the sum of the compliance of each of the components in the system,

$C = (\frac{dV}{dP}) = \sum(C_f + C_t)$ in MKS units, where C_f equals the compliance of the fluid, any materials that come in contact with the fluid, and any air in the system and C_t equals the compliance of the transducer and any connecting apparatus. The system damping coefficient may be expressed by the equation $\xi = \frac{32\eta}{D^3}\sqrt{\frac{LC}{\pi\rho}}$.

Symbol	Variable	Units
L	tube length	meters
ξ	system damping coefficient	NA
f_0	natural frequency	HZ
ρ	density of the liquid	kg per cubic meter
A_0	amplitude when $f = 0$.	MKS
A	signal amplitude	MKS
f	frequency	HZ
C	system compliance	meters^5 per Newton ($m^3/Nt/m^2$)
η	fluid viscosity	NtS/m^2

Commercially available fluid lines which are used to measure patient arterial or venous blood pressure during surgery typically have diameters of a few millimeters or larger and a natural frequency on the order of 30 Hz. Since the natural frequency is proportional to diameter and inversely proportional to the square root of compliance, a guide wire fluid line with a diameter equal to a fraction of a millimeter must have a dramatically reduced system compliance to maintain a 30 Hz or larger bandwidth.

Similarly, the damping coefficient depends on the inverse cube of the fluid column diameter with larger diameter conventional lines under damped ($\xi < 1$). To prevent over damping in small guide wire fluid lines, the compliance of the system must also be dramatically reduced.

Experimental work has confirmed the theoretical work which suggests that the compliance of a hollow 0.014 inch guide wire and a proximal pressure transducing apparatus are crucial to the frequency response of the phasic pressure wave. Any soft plastic or rubber materials present, even in small quantities anywhere in the system, can dampen the signal. Wherever possible, minimally compliant materials may then be used. Small amounts of air trapped in the system can also dampen the signal. To achieve adequate bandwidth and a damping coefficient less than unity, the amount of entrapped air should be less than 0.007 mm^3. In addition, typical commercially available pressure transducers contain compliant adhesives and gels, which also dampen the signal. If necessary custom pressure transducers may be manufactured. Finally, it has been determined that the total fluid volume of the system should be minimized (less than about 0.1 cc) to transmit good phasic signals. This is because water in a fluid line and connector has a very small but not negligible compliance which is proportional to the

total volume of water in the system.

Refer now to Figures 1a-2d, a first embodiment of the invention depicts a guide wire having an elongate body 5 with proximal and distal ends and at least one lumen 11 therethrough. Each lumen 11 has a proximal opening corresponding to the proximal end of elongate body 5 and a distal opening corresponding to the distal end

of elongate body 5. At the distal end of elongate body 5 an atraumatic tip 1 is bonded to the distal opening of the lumen.

In Figures 2a-2d an example of an atraumatic tip 1 is shown where the atraumatic tip 1 is a spring tip. Spring tips are well known in the guide wire art and the following description discloses some but not all of the possible materials and methods of construction. A tapered shaft 34 is bonded at its proximal end into the distal opening of lumen 11. Shaft 34 may be welded, adhesively attached, or bonded to elongate body 5 in any way such that a fluid tight and pressure tight seal is formed. Shaft 34 is brazed to a coil 33 at its distal end to form a bead 32. Coil 33 may be made of a radio-opaque material such as, platinum-iridium alloy or other suitable medical grade radio-opaque alloy, to make the spring tip more visible under fluoroscopy. Coil 33 has a diameter of about .010-.020" and encircles shaft 34 along its entire length. Coil 33 is further attached to shaft 34 by welding the proximal portion of coil 33 to the distal end of elongate body 5. Those skilled in the art will recognize that other atraumatic tips 1, such as a polymer covered tip, could be used with the present invention.

Elongate body 5 has holes 15 located near the distal end of elongate body 5. Holes 15 pierce elongate body 5 and make a complete fluid path from the exterior of the distal end of elongate body 5 via lumen 11 to the proximal end of elongate body 5. Holes 15 may be circular, oval, or slot-like and, in the preferred embodiment, each elongate body 5 has at least two and preferably 4 holes 15 in communicating with each lumen 11 therein.

In order to effectively communicate pressure from holes 15 along lumen 11 to the proximal end of elongate body 5, the entire fluid pathway must be so rigid as to be

non-compliant, ie. the flexing of materials in contact with the fluid will not absorb any pressure changes. In addition, lumen 11 must be filled with a non-compliant fluid. Suitable fluids include water, heparin, ringers, fluids drugs, saline, silicone oil, gel, silicone gel, alcohol, or perfluorocarbon. These fluids can be pre-filled when the device is manufactured or injected into the device just prior to use. The material that surrounds lumen 11 must also be non-compliant. Suitable materials include Nitinol™ , stainless steel, polycarbonate, or other non-compliant medical grade alloys, polymers, or composites. The resulting structure insures that a displacing force on the exterior of the distal end of elongate body 5 will cause a force equal to the displacing force to be communicated to the proximal end of elongate body 5 via the fluid in lumen 11.

It is also preferable to have each hole 15 act as a one way fluid valve and a two way pressure valve, as shown in Figure 1b and 1c. That is, each hole 15 may allow fluid, including fluid air, to pass only from the interior of elongate body 5 to the exterior while also allowing pressure to be communicated across the valve. This is preferably accomplished by surrounding the hole 15 with a PTFE membrane sleeve 16 as shown in Figure 1b. One example of a material that may be used as the membrane sleeve 16 is Gortex™ with a maximum pore size of 4 microns. Gortex™ is constructed such that its pore structure allows fluid to pass through the membrane in only one direction. As a membrane though, a sleeve made of this material still communicates pressure in either direction. A sleeve of this or other suitable material may be placed over each hole 15 and bonded at each end of the sleeve. Further, a single sleeve may be placed over several holes 15 and bonded on each side of each hole 15.

Alternatively, a membrane sleeve 16 may made be of an elastomer like urethane, a glass fiber composite, or an acrylic copolymer. Use of any of these materials would allow pressure to be communicated across the sleeve 16 but would

not allow fluid to pass through the sleeve 16. This type of membrane sleeve 16 may be bonded to the elongate body 5 on only one side, preferably the proximal side, of hole 15 as shown in Figure 1c. In this manner of construction, a positive pressure differential between the interior of elongate body 5 and the exterior of elongate body 5 would force any air and or other fluid out of the interior of elongate body 5 through the unbonded end of the membrane sleeve 16. When the pressure on the exterior of elongate body 5 is equal to or greater than that of the interior, the sleeve 16 would seal the hole 15 to any fluid flow. As an elastomer, sleeve 16 would continue to flex toward the lower pressure side of hole 15 and as such would allow pressure to pass through hole 15 without the transfer of fluid.

Referring back again to Figure 1a, a high pressure transducer 30, preferably with a full scale pressure capability of 10-1,000 times normal blood pressure is sealingly connected and in fluid communication with lumen 11 in the proximal end of elongate body 5. Use of a high pressure transducer which has a very high signal to noise ratio allows physiologic pressure variations to be sensed with only a tiny displacement of the fluid column. Thus relatively rapid pressure variations are communicated accurately through the very small displacement of a small mass of fluid within a non-compliant system. An example of a high pressure transducer 30 may be a silicon piezoresistive pressure transducer, an example of which is the Lucas Nova™ sensor, NPC-102. Pressure transducer 30 preferably has a 1 mmHg sensitivity and a full scale pressure capability which, as previously described, is 10-1,000 times greater than the range of interest. Where, preferably the use of a 500 psi full scale transducer with the invention has been found to provide good results for measuring blood pressure (approximately 5 psi).

In an alternative embodiment, a dual transducer system may be used to compensate for inaccuracies introduced by variations in the damping coefficient due to mechanical interface variations like air introduced into the system and mechanical

tightness. A dual transducer system works by using two identical transducers 30 to create a reference pressure in one transducer 30 and a sensed pressure in the other transducer 30. The reference signal is then filtered to contain a DC or static pressure signal which is subtracted from the dynamic pressure signal. The difference is the offset connect pressure.

Figure 2a shows one approach to the construction of the distal end of the embodiment of Figure 1a. In Figure 2a, elongate body 5 is composed of a core member 6, having a lumen 11 therethrough and an traumatic tip 1 as previously described. Core member 6 may be made of Nitinol™ or any other suitable medical grade alloy and is preferably made of stainless steel. Core member 6 may be either standard guide wire length, about 150-175 cm, or standard exchangeable guide wire length, about 300 cm. At its proximal end core member 6 has an outer diameter of .014" and an inner diameter of .008". At the distal end of core member 6 the outer diameter of core member 6 tapers to .011". A suitable medical grade polymer 7 covers the tapered section of core member 6 making the elongate body have a uniform diameter along its entire length, e.g. .003" of polymer 7 surrounds the distal end of core member 6. Through the distal section of core member 6 are holes 15 which allow fluid communication between the interior and exterior of core member 6. As previously described, holes 15 may be covered by a membrane sleeve 16 as shown in Figure 2b.

Figures 2c illustrates a second approach to the construction of the distal end of the embodiment of Figure 1a. In Figure 2c elongate body 5 is composed of a core member 6 and hypotube 8. Elongate body 5 has a lumen 11 therethrough and an atraumatic tip 1 as previously described. Core member 6 may be made of stainless steel or any other suitable medical grade alloy and is preferably made of Nitinol™. Elongate body 5 may be either standard guide wire length, about 150-175 cm, or standard exchangeable guide wire length, about 300 cm. The distal end of core

member 6 tapers to an outer diameter of .0105" and is suitable for insertion into hypotube 8. The distal end of core member 6 fits within hypotube 8 which has an outer diameter of .014" and an inner diameter of .0105". Core member 6 may be bonded or press fit together with hypotube 8 and may be made of any medical grade metal but is preferably Nitinol™. Through the distal section of hypotube 8 are holes 15 which allow fluid communication between the interior and exterior of hypotube 8. As previously described, holes 15 may be covered by a membrane sleeve 16 as shown in Figure 2d.

Figures 3a and 3b depict a method of connecting the proximal end of elongate body 5 to a pressure transducer 30. Gripper 20 is a side loading guide wire gripping device as disclosed in US Patent number 4,829,999, herein incorporated by reference. Gripper 20 is molded onto stopcock 25 at its proximal end. Stopcock 25 has a fluid port 22 adapted to receive a syringe and a valve 26 that directs fluid flow. Valve 26 may be aligned to make a fluid path between port 22 and gripper 20, between the gripper 20 and the pressure transducer 30, or to a closed position. Stopcock 25 can be made of any medical grade, non-compressible material and is preferably made of polycarbonate. Figure 3b is an end view of gripper 20.

In Figure 3c a gripper 20 like that of the previous embodiment is molded onto a connector 27. Connector 27 has three ports. The first and second ports are attached to pressure transducers 30. The third port is attached to gripper 20. Within the third port is a neoprene o-ring 28 that provides a fluid tight seal capable of holding a pressurized liquid or gel within connector 27. Examples of these liquids or gels include water, saline, silicone oil, silicone gel, alcohol, or perfluorocarbon. When elongate body 5 is inserted into connector 27 it passes through the o-ring 28 and creates a fluid communication path between the pressure transducers 30 and lumen 11 of elongate body 5.

In use either of the connector assemblies shown in Figures 3a and 3c could be used with either of the tip configurations shown in Figures 2a-2d. However, the actual method of use for each configuration will vary depending on the choice of connector assembly. Use of the connector assembly of Figure 3a and 3b requires the compression of finger pads 21, thereby opening a channel in gripper 20. The core member 6 may then be laid in the channel and then slid into stopcock 25. Finger pads 21 may then be released, thereby securing the hypotube within stopcock 25. The elongate body 5 may then be positively prepped by orienting the valve 26 such that there is a fluid path between the lumen 11 and port 22. A syringe may be fitted into port 22 and fluid injected until all air is forced through holes 15. Valve 26 may then be oriented such that there is a fluid path between holes 15 and the pressure transducer 30. This embodiment would then be used like a standard guide wire.

Use of the connector assembly of Figure 3c requires that the elongate body 5 be positively prepped by injecting a fluid into the proximal end of lumen 11 until all air is expelled from holes 15. The guide wire may then be used like any other guide wire. When the guide wire is located in a position where it is desired to measure pressure, the pre-filled connector assembly of Figure 3c is attached to the proximal end of the core member 6. Compression of finger pads 21 opens a channel in gripper 20. The core member 6 may then be laid in the channel slid through o-ring 28 and into connector 27. Finger pads 21 may then be released, thereby securing the hypotube within connector 27. When transducers 30 are connected to circuitry as describe for a dual sensor system, a pressure measurement can be taken.

Figure 4 shows an embodiment of the invention with more than one lumen. This embodiment also may have an atraumatic tip 1, as previously described, attached to the distal end of an elongate body 5. Elongate body 5 may be 150-300 cm in length. Elongate body 5 is shown in Figure 4 as having two lumens 11 but may have more than two lumens. Each lumen 11 is in fluid communication with a separate set

of holes 15, as previously described. Each set of holes 15 is longitudinally displaced relative to the other sets of holes 15. Longitudinal displacement of each set of holes 15 allows pressure to be measured in multiple locations within the vasculature simultaneously. Each set of holes 15 is in fluid communication, via lumen 11, with a transducer 30, as previously described. Each lumen 11 is formed by a surrounding non-compliant material like stainless steel, polyimide, a polyimide composite, Nitinol ™, or other suitable medical grade metal or polymer. At the proximal end of elongate body 5 there is a connector 27 which is removeably attached to elongate body 5. Alternatively, the embodiment of Figure 4 may also include membrane sleeves 16 covering holes 15 (not shown).

In use, the embodiment of Figure 4 would be prepped be flushing a non-compliant liquid or gel through lumens 11 until all air has been expelled from through holes 15. The device can then be advanced through a patient's vasculature to a point where it is desired to measure pressure. As an example, the device could be advance until the distal set of holes 15 is on the distal side of a vascular lesion. This would leave the proximal set of holes 15 on the proximal side of a lesion. Connector 27 may then be fit onto the proximal end of the device such that each lumen 11 is in fluid communication with a pressure transducer 30. In the example, pressure could then be measured on each side of the lesion. This information will give the users of the device a pressure gradient across the lesion and another tool in determining the extent of the occlusion.

Refer now to Figure 5 which depicts an alternative embodiment of the pressure sensing guide wire where body portion 110. A spring tip 113, as is commonly known in the art, is attached to the distal end of body portion 110. Spring tip 113 may have a safety ribbon 117 and may be about 1-4 cm long and is preferably about 3 cm long. Distal tube 120 may be formed of a super elastic material. The proximal end of safety ribbon 117 may be press fit into distal tube 120, soldered to distal tube 120, or

preferably distal tube 120 is chilled into its Martensite phase and then ribbon 117 fit into place. When distal tube 120 is allowed to return to ambient temperature a compressive bond is formed.

Distal tube 120 maybe be any medical grade super elastic material and preferably is Nitinol with an Austinite finish temperature of 10° C ±10 as supplied by Raychem Corp. of California or the Nitinol Device Corp of California. The outside diameter of distal tube 120 may be about .0136 inches, the inside diameter may be about .0075 inches, and the length may be about 12 inches. Near the distal end of distal tube 120 are holes 123. There may be as few as one hole 123 but preferably there are about 6 holes 123 arranged in a helical pattern around distal tube 120 and spaced along an axial length of .020-.040 inches. While no more than one hole 123 is required to provide a phasic pressure signal, several holes 123 ensure that the vessel wall or other material does not plug distal tube 120. Holes 123 may be electron discharge milled into distal tube 120 and electro-etched to remove any burrs. The exterior of the distal end of distal tube 120 may be further electro-etched to increase the flexibility of distal tube 120.

Alternatively, distal tube 120 may be made of a polymer/wire composite (not shown) as disclosed in WO 93/20881 to Pray et al., which is herein incorporated by reference. There may be one or more wires arranged in one of a variety of different patterns such as helix. This alternative distal tube 120 may be more flexible than a Nitinol distal tube 120 while maintaining a minimally compliant fluid path and the performance characteristics of a coronary guide wire.

The distal end of proximal hypotube 125 is bonded to the proximal end of distal tube 120. Proximal hypotube 125 may be press fit into distal tube 120, soldered to distal tube 120, or bonded in the method previously described. The joint between proximal hypotube 125 and distal tube 120 may be a stepped joint. However, to reduce the likelihood of breakage an angled joint as shown in Figure 5 is preferred. Proximal hypotube 125 may be made of any medical grade alloy and is preferably made of 304V stainless steel which may be heat treated for resilience and plug drawn for smoothness. The inside diameter of proximal hypotube 125 may be about .0075 inches, the outside diameter about .0136 inches, and the length about 160 inches.

Flushing connector 115 may be bonded to the proximal end of proximal hypotube 125 or flushing connector 115 may be adapted to be releasably connected to any physiological fluid line. Flushing connector 115 may have a flushing port 127 and a stop cock 130. Integrally formed with or bonded to flushing connector 115 is pressure transducer 133. Pressure transducer 133 may be a commercially available solid state pressure transducer such as Model #109 available from Lucas Nova Corporation, in Freemont, CA. Alternatively a custom pressure transducer may be manufactured by modifying the Model #109 from Lucas Nova Corporation which reduces the RTV glue used to bond the sensor to the substrate. The pressure transducer 133 may have electrical leads suitable for connection to standard monitoring systems.

Figure 6 depicts a another embodiment of the invention with body section 110 the same as previously described for the embodiment of Figure 5. An optically clear view tube 137 is bonded to the proximal portion of proximal hypotube 125. View

tube 137 may be made of glass, polyimide, a fused silica capillary as sold by Polymicro Technologies of Phoenix, AZ, or any other optically clear minimally compliant material. Optical connector 135 may be bonded or releasably attached to the exterior of the proximal end of proximal hypotube 125 or may be adapted to be releasably connected to any physiological fluid line. Optical connector 135 houses a light source 140 which is aligned to shine through view tube 137. Light source 140 may be a light bulb with a lens or a laser diode but preferably is a light emitting diode. Light source 140 may produce a variety of wavelengths of light and will preferably produce infrared light. Optical connector 135 may also house a photodetector 143 aligned to receive light from light source 140 that has passed through view tube 137.

Within the proximal end of view tube 137 is an air column 145. Air column 145 is trapped by pressure communicating fluid 148. Pressure communicating fluid 148 may be any fluid which is bio-compatible, opaque to light from light source 140, minimally evaporative, and non-corrosive, examples of which may include ferrofluids, cotton seed oil, vegetable oil, saline, and water. The guide wire of this embodiment may be prepped prior to packaging. Specifically an air column 145 needs to be put in place in the proximal end of view tube 137, the pressure communicating fluid 148 loaded into view tube 137, and a temporary seal (not shown) placed around holes 123. The interface between the air column 145 and the pressure communicating fluid 148 must be aligned so as to cause a shadow between light source 140 and photodetector 143. Changes in fluid pressure at the distal end of the guide wire will cause the interface to move and the change in light detected by the photodetector can be interpreted as pressure changes. Preferably an air column which

is about 0.01 inches long in a tube of 0.008 inches inside diameter is desired to give a compliance of about $8x10^{-17}\ m^5/Nt$ and corresponds to a natural frequency of about 100 Hz and a damping coefficient of near unity. Further, the guide wire may be connected to a view tube 137 which has an outside diameter which is smaller than the inside diameter of the guide wire thereby allowing linear movement of the fluid column for a given change in distal pressure.

In use the embodiments shown in Figures 5 and 6 may be prepped by the manufacturer prior to packaging or by the user just prior to the procedure. When prepped by the user, the common technique of a positive prep may be used. This technique involves flushing fluid from the proximal end the guide wire, out of the distal end of the guide wire and thereby flushing any air from the system. A negative prep may also be used by creating negative pressure at the proximal end of the guide wire, as by a syringe, and drawing any air from the system while filling the guide wire with a fluid. Once prepped, the guide wire may be used in the same way as a conventional guide wire. That is, the wire is inserted into the vasculature and advanced to a desired treatment site. Once at the treatment site the guide wire, unlike common coronary guide wires, may be used to sense phasic pressure. Pressure may be sensed at different locations. For instance pressure can be measured on either side of a lesion. If a therapeutic procedure is desired, another device, like an angioplasty balloon catheter, may be advanced over the wire. Pressure may also be measured at different times such as during, before, or after a procedure.

While the specification describes the preferred designs, materials, methods of manufacture and methods of use, those skilled in the art will appreciate the scope and spirit of the invention with reference to the appended claims.

We claim:

1. A medical pressure sensor comprising:

a body portion having a proximal end, a distal end, and a lumen extending therethrough for communicating pressure from the distal end of the body portion to the proximal end of the body portion, the body portion having a compliance which includes the compliance of the body portion and any fluid therein; and

a transducer positioned near the proximal end of the body portion and in fluid communication with the lumen, the transducer having a compliance, wherein the body portion and the transducer have a compliance C which is equal to the sum of the compliance of the body portion and the transducer,

$$C < \left(\frac{D}{4f_0}\right)^2 x \frac{1}{\pi\rho} \text{ and } C < \left(\frac{\xi D^3}{32\eta}\right)^2 x \frac{\pi\rho}{L}$$

where D is less than about 0.0013 meters, f_0 less than about 30 Hz, and ξ is less than about 3.0.

2. A pressure sensing device having a total compliance, the device comprising:

an elongate body having length of about 1-4 meters, a pressure communicating lumen extending therethrough, an inner diameter of less than about 0.0013 meters, and a proximal end; and

a transducer attached to the proximal end of the elongate body and in fluid communication with the lumen, the total compliance of the pressure sensing device less than about $4x10^{-14}\ m^5/Nt$.

3. The pressure sensing device of claim 2 wherein the total compliance of the device includes the compliance of a volume of liquid disposed thereon, the volume of liquid being less than about one cubic centimeter.

4. The pressure sensing device of claim 2 wherein the total compliance of the device includes the compliance of a volume of entrapped air disposed thereon, the volume of entrapped air being less than about 0.004 cubic centimeters.

5. A method of sensing a phasic pressure signal within a body lumen comprising:

providing an elongate body having a proximal end, a distal end, a pressure communicating lumen therethrough, a fluid within the pressure communicating lumen, a transducer attached to the proximal end of the elongate body and in fluid communication with the pressure communicating lumen, and a system compliance of less than about 4×10^{-14} m^5/Nt, the pressure communicating lumen having a diameter of less than about 0.0013 meters;

inserting the distal end of the elongate body into the body lumen;

advancing the elongate body to a position within the body lumen; and

sensing the phasic pressure signal at that position within the body lumen.

6. The method of sensing a phasic pressure signal within a body lumen of claim 5 further comprising:

providing a catheter having a lumen therethrough; and

advancing the catheter over the elongate body after the elongate body has been advanced to the position within the body lumen.

7. The method of sensing a phasic pressure signal within a body lumen of claim 6 further comprising:

conducting a therapeutic procedure with the catheter after the catheter has been advanced to the position within the body; and

sensing the phasic pressure signal before, during or after the therapeutic procedure has been conducted.

8. The method of sensing a phasic pressure signal within a body lumen of claim 7 further comprising:

sensing the phasic pressure signal before and after the therapeutic procedure.

9. A connector suitable for removeably connecting to a medical pressure sensing instrument, the connector comprising:

a body portion having an interior and a port suitable for providing fluid communication between the medical pressure sensing instrument and the interior of the body portion, the body portion having a compliance; and

a pressure transducer attached to the body portion and in fluid communication with the interior of the body, the pressure transducer having a compliance, wherein the sum of the compliance of the body portion and the compliance of the pressure transducer is less than 4×10^{-14} m^5/Nt.

10. The connector of claim 9 further comprising:

a flush port in fluid communication with the interior of the body portion; and

a stop cock positioned such that fluid communication between the interior of the body portion and the flush port may be blocked.

11. The connector of claim 9 wherein the pressure transducer is a solid state pressure transducer.

12. The connector of claim 9 wherein the pressure transducer comprises:

a light source attached to the body portion and aligned to shine through the medical pressure sensing instrument; and

a photodetector attached to the body portion and positioned to detect light shined through the medical sensing instrument.

13. The connector of claim 12 wherein the light source is a light emitting diode.

14. The connector of claim 12 wherein the light source emits infrared light.

15. A guide wire comprising:

a first proximal tube having a distal end; and

a second distal tube having a proximal end, the proximal end of the second tube bonded to the distal end of the first tube and the second tube being more flexible than the first tube.

16. A medical pressure sensing device, comprising:

an elongate body having a proximal end, a distal end, at least one lumen therethrough, and at least one hole near the distal end of the elongate tube to provide pressure communication between the lumen and a pressure source external to the elongate body;

a connector attached to the proximal end of the elongate body and in fluid communication with the at least one lumen therein; and

at least one pressure transducer attached to the connector, wherein the at least one pressure transducer is adapted to have a full scale pressure capability which is 10-16,000 times greater than the range of interest and the at least one pressure transducer is in fluid communication with the at least one lumen.

17. A medical pressure sensing device as in claim 16, wherein the at least one lumen is filled with a noncompliant fluid.

18. A medical pressure sensing device as in claim 17, wherein the noncompliant fluid is a fluid selected from the group consisting of water, saline, silicone oil, perfluorocarbon, gels, silicone gel, and alcohol.

19. A medical pressure sensing device as in claim 17, wherein at least one valve is attached to the distal end of the elongate body such that the at least one valve covers the at least one hole.

20. The medical pressure sensing device as in claim 19, wherein the valve allows fluid to flow out of the lumen but not into the lumen and allows pressure to be communicated across the valve.

21. The medical pressure sensing device as in claim 20, wherein the valve comprises a PTFE membrane attached to the distal end of the elongate body to cover the hole.

22. A medical pressure sensing device as in claim 16, wherein the connector has a first port adapted to connect to the proximal end of the elongate body, a second port adapted to connect to a pressure transducer, and at least one additional port.

23. A medical pressure sensing device as in claim 16, wherein the connector is made of polycarbonate.

24. A medical pressure sensing device as in claim 16, wherein two pressure transducers are in fluid communication with each at least one lumen.

25. A medical guide wire comprising:

an elongate body having a proximal end, a distal end, a non-compliant lumen extending between the proximal end of the elongate tube and the distal end of the elongate tube, and at least one hole near the distal end of the elongate tube to provide pressure communication between the lumen and a pressure source external to the elongate body;

a noncompliant connector attached to the proximal end of the elongate body in fluid communication with the non-compliant lumen; and

at least one pressure transducer attached to the noncompliant connector.

26. A medical guide wire as in claim 25, wherein the elongate tube includes a metallic tube having a tapered distal section and a polymer coating surrounding the distal section.

27. A medical guide wire as in claim 25, wherein the elongate body comprises:

a first metallic tube having a tapered distal section; and

a second noncompliant tube attached to a portion of the distal section of the first metallic tube and extending distally of the first metallic tube.

28. A medical guide wire as in claim 27, wherein the first metallic tube includes stainless steel and the second noncompliant tube includes a shape memory alloy.

29. A medical guide wire as in claim 25, wherein the at least one pressure transducer is adapted to have a full scale pressure capability which is 10-25,000 times greater than the range of interest.

30. A medical guide wire as in claim 25, wherein the at least one lumen is filled with a noncompliant fluid.

31. A medical guide wire as in claim 30, wherein the noncompliant fluid is a fluid selected from the group consisting of water, saline, silicone oil, gels, silicone gel, and alcohol.

32. A medical guide wire as in claim 25, wherein the at least one hole is sealed by a valve which allows fluid to flow out of the lumen but not into the lumen and allows pressure to be communicated across the valve.

33. A medical guide wire as in claim 25, wherein the noncompliant connector has a first port adapted to connect to the distal end of the elongate tube, a second port adapted to connect to a pressure transducer, and at least one additional port.

34. A method of measuring pressure changes across a vessel site comprising:

inserting an elongate medical pressure sensing device into the vessel, the device having a proximal end, a distal end, at least two lumens therethrough, at least two laterally displaced sets of holes near the distal end, wherein at least one set of holes provides pressure communication between each of the lumens and a pressure source exterior of the elongate medical pressure sensing device, a noncompliant connector attached to the proximal end of the elongate medical pressure sensing device in fluid communication with the lumens therein, and at least two pressure transducers attached to the non-compliant connector wherein at least one pressure transducer is in fluid communication with each lumen;

advancing the elongate medical pressure sensing device through the vessel to a point where one set of holes is distal of the site and another set of holes is proximal to the site; and

reading pressure from the distal side of the lesion and the proximal side of the lesion.

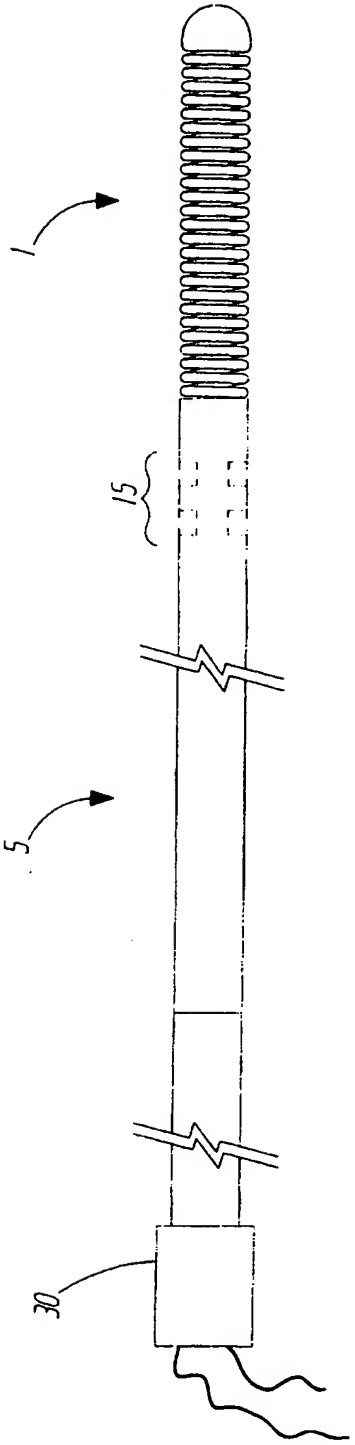

FIGURE 1a

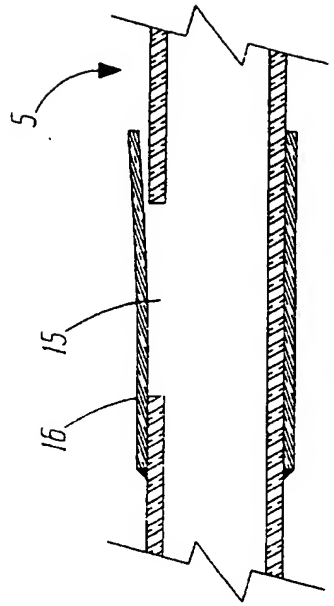

FIGURE 1c

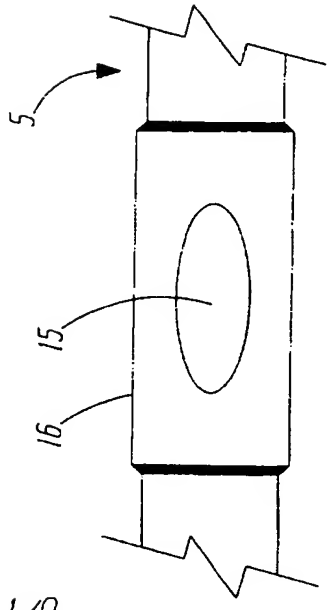

FIGURE 1b

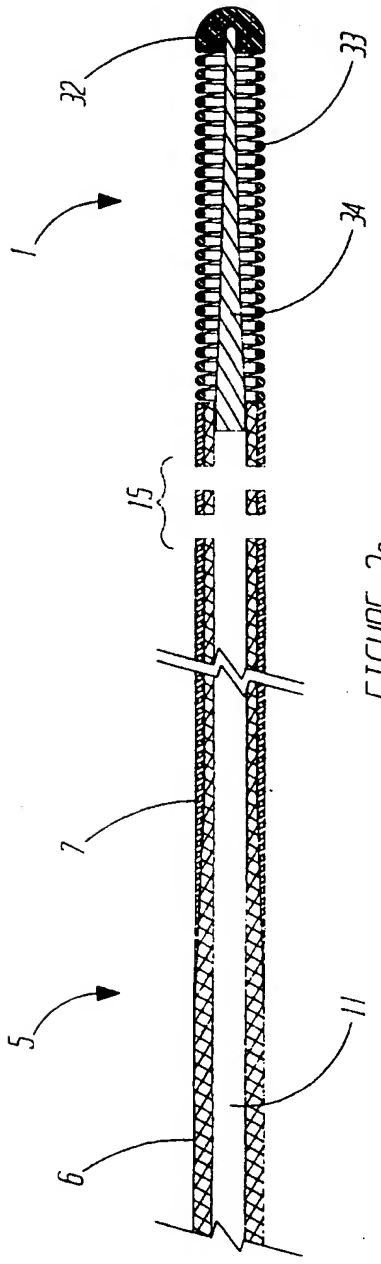

FIGURE 2a

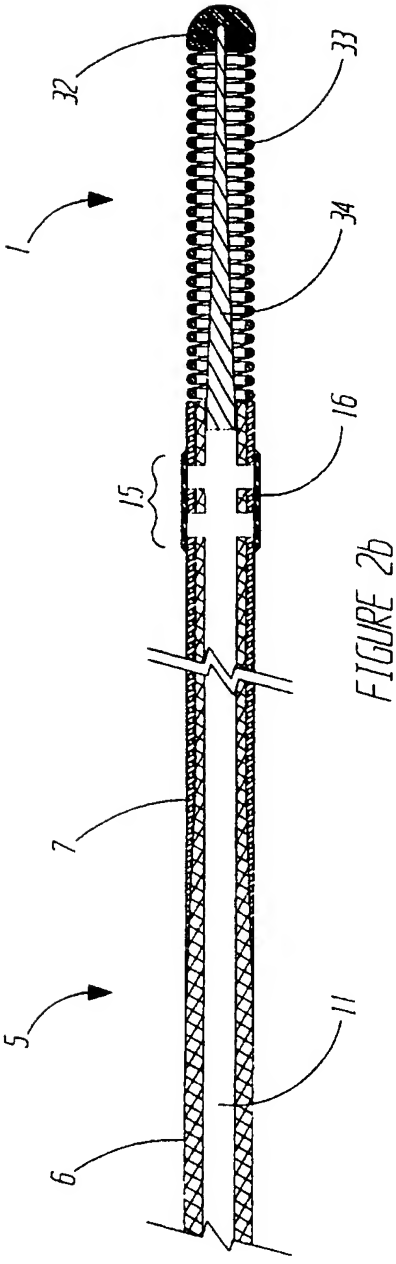

FIGURE 2b

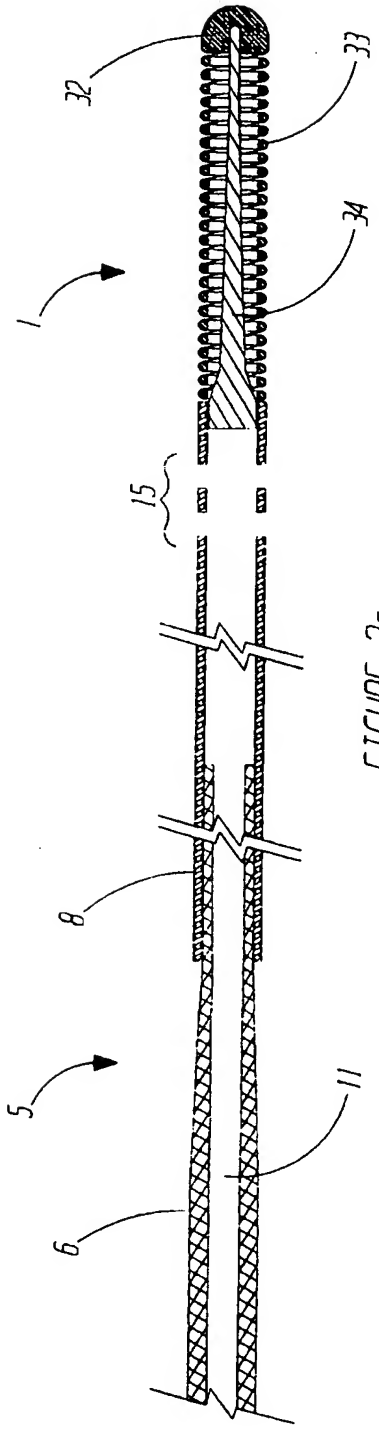

FIGURE 2c

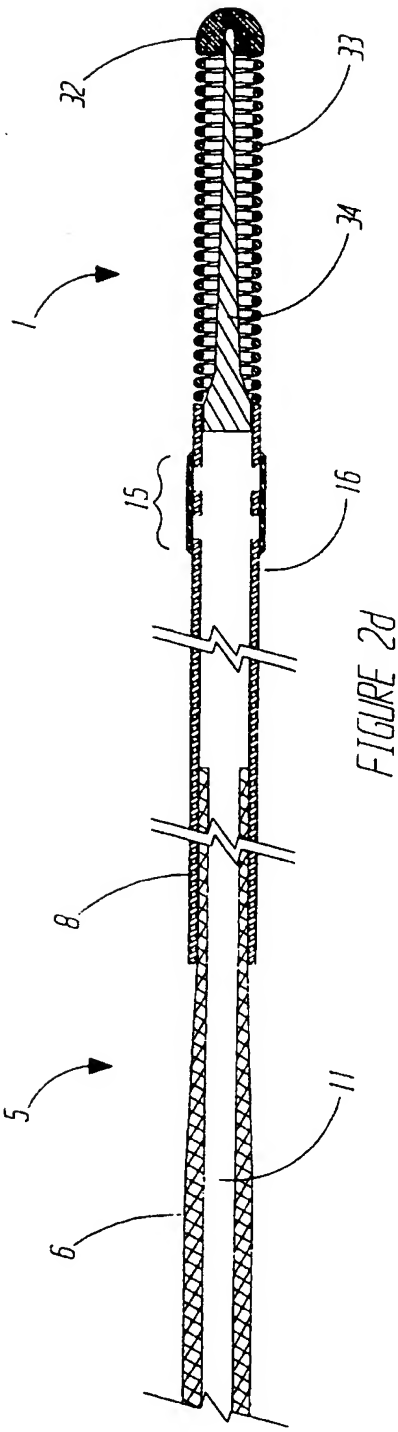

FIGURE 2d

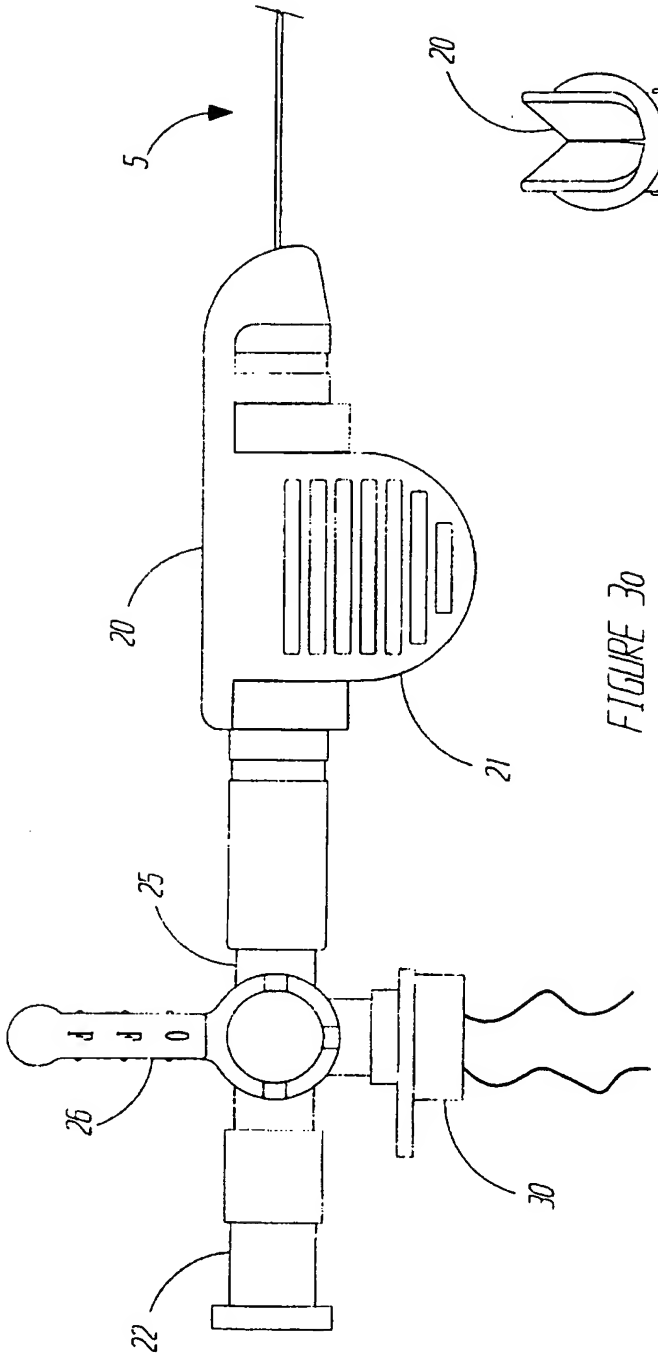

FIGURE 3a

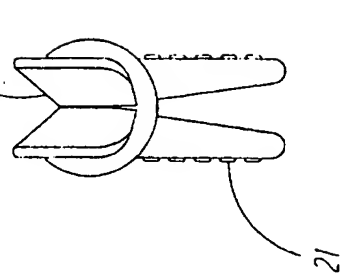

FIGURE 3b

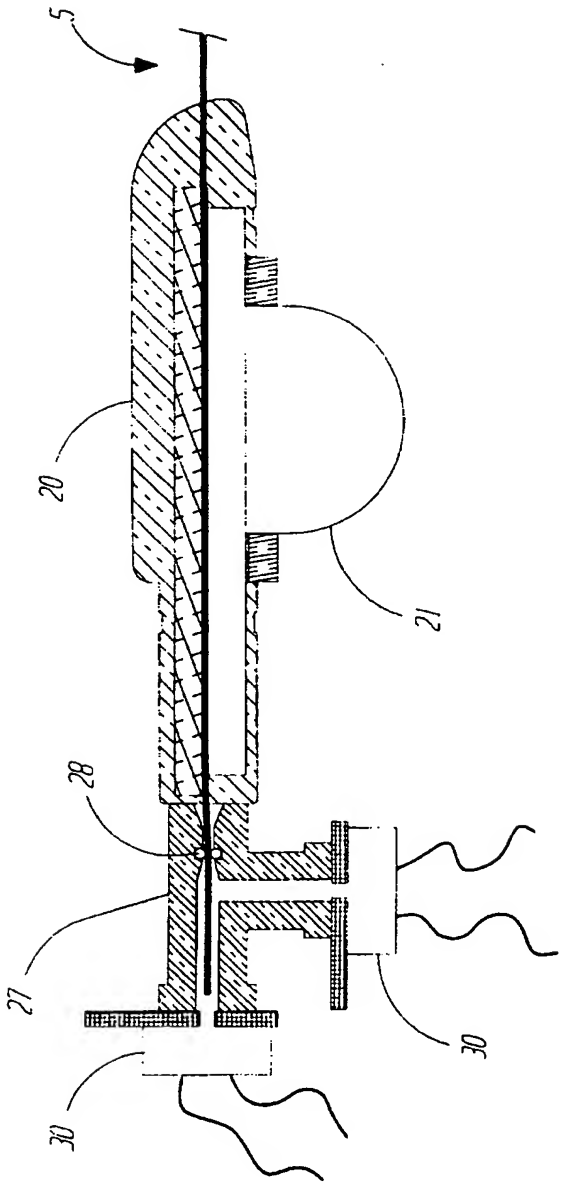

FIGURE 3c

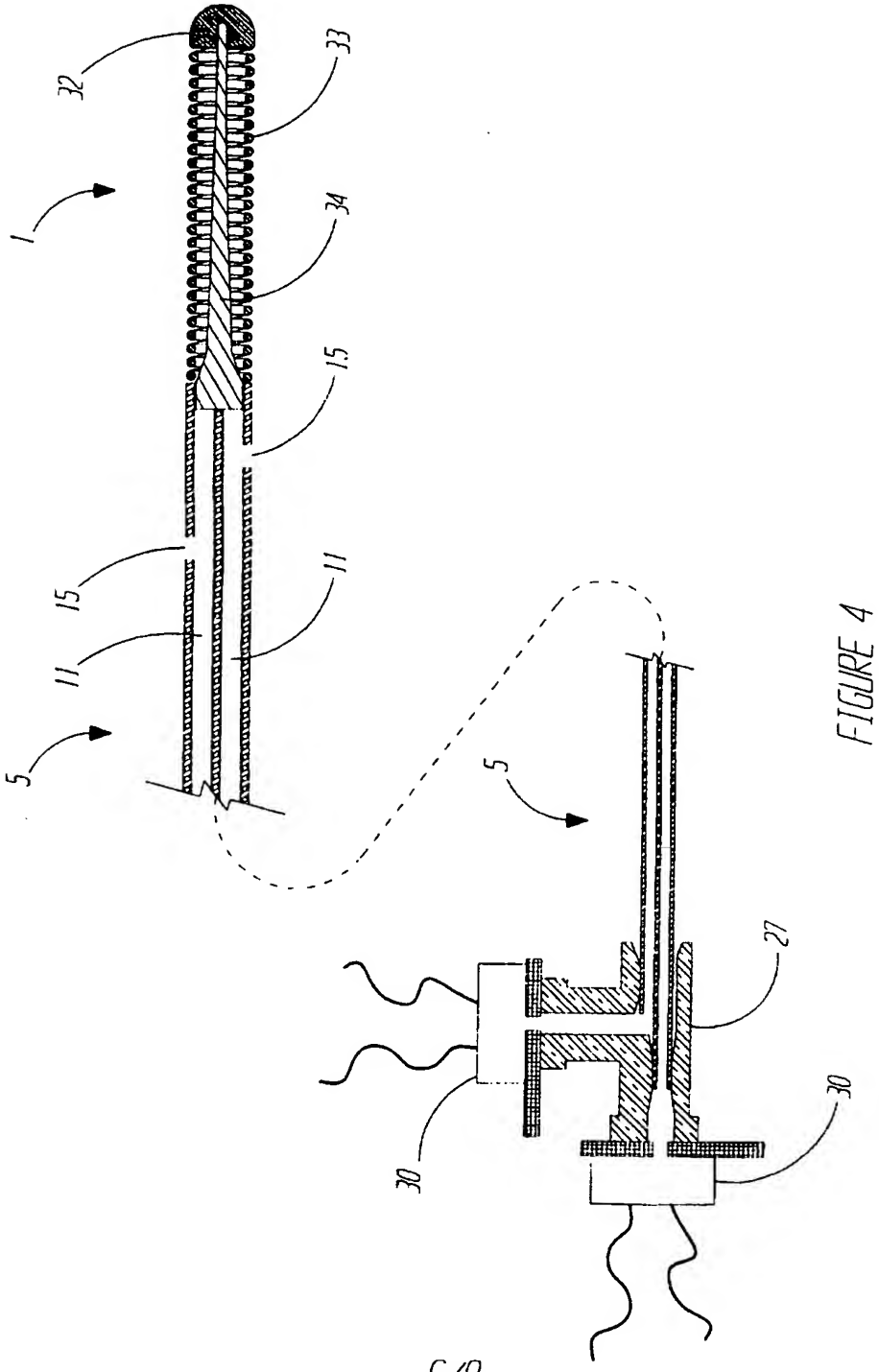

FIGURE 4

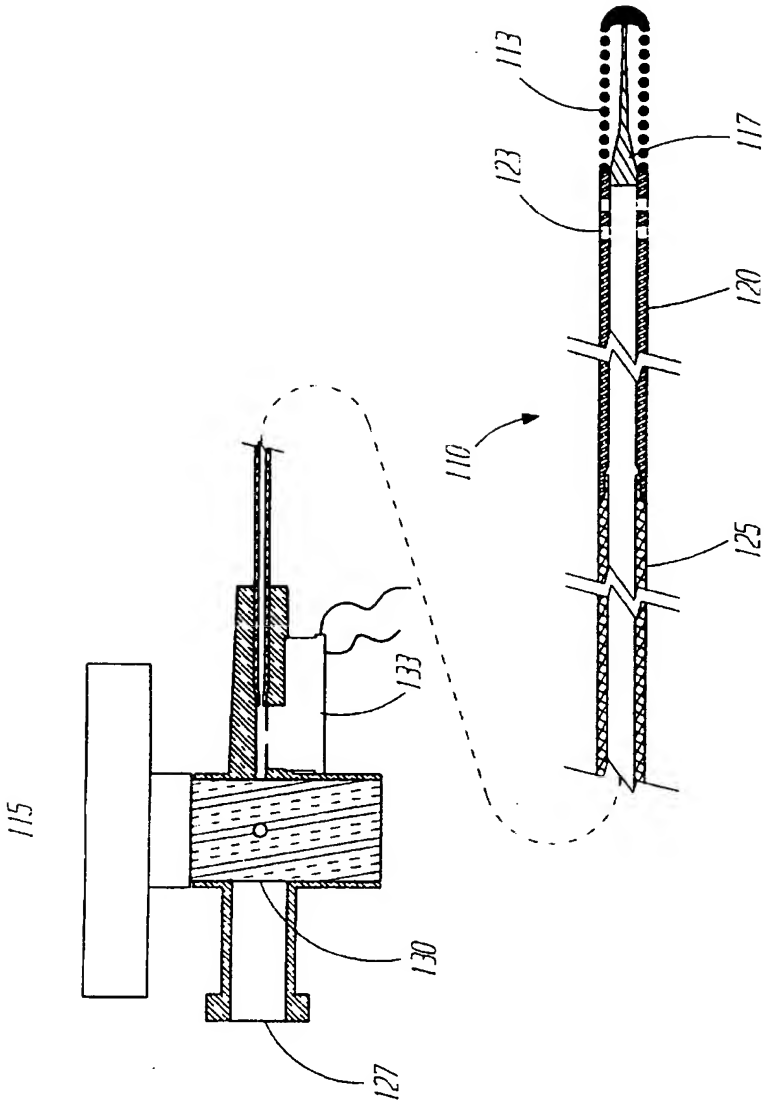

FIGURE 5

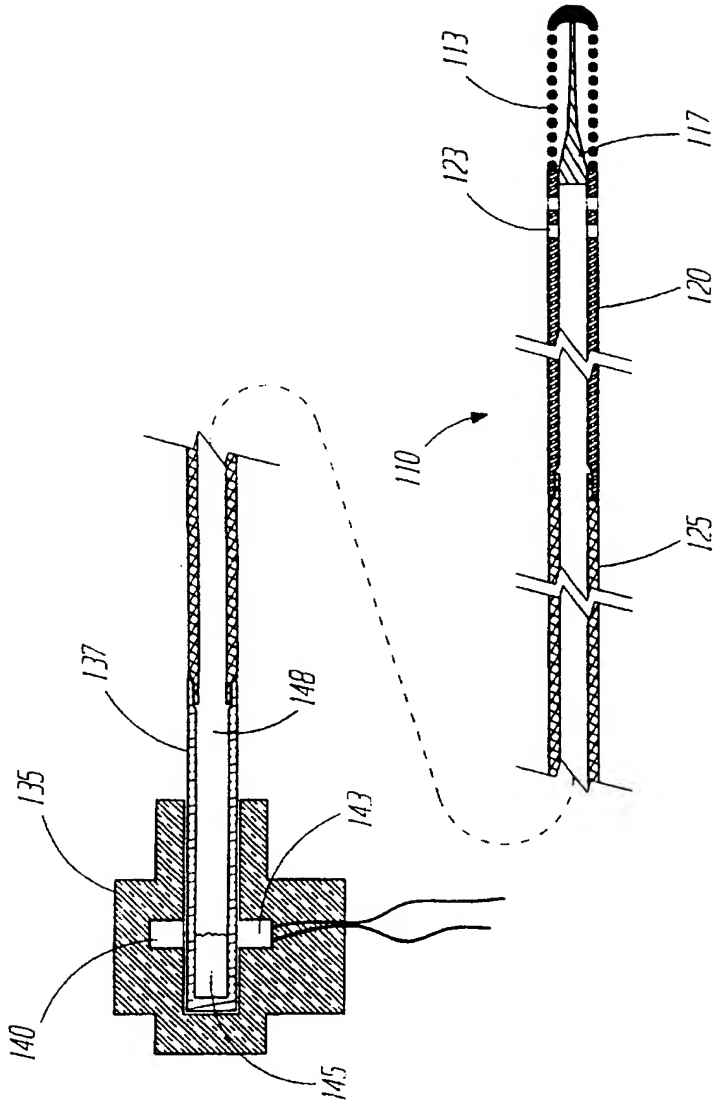

FIGURE 6

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/US 97/04814

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/0215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 108 369 A (D. GANGULY ET AL.) 28 April 1992	2,9, 16-18
A	see column 3, line 31 - line 52	22,24
A	see column 4, line 31 - column 5, line 25	25,30

A	WO 95 06433 A (ROCKY MONTAIN RESEARCH, INC.) 9 March 1995	9-12, 16-18
A	see page 9, line 5 - page 10, line 21	22,24
A	see page 11, line 29 - page 13, line 11	25,30

A	WO 89 10089 A (MILLAR INSTRUMENTS, INC.) 2 November 1989	9-11, 16-20
A	see page 7, line 22 - page 8, line 33	30-32
	see page 10, line 4 - line 13	

P,A	WO 96 32056 A (E. BILLIET) 17 October 1996	16-18,22
A	see page 3, line 12 - line 31	24,25,30
	see page 7, line 18 - page 8, line 22	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
15 July 1997	22. 07. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Rieb, K.D.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

I national application No.
PCT/US 97/04814

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 5-8,34
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Intern. al Application No
PCT/US 97/04814

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 5354220 A	11-10-94
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WO 9506433 A	09-03-95	US 5423323 A	13-06-95
WO 8910089 A	02-11-89	US 4901731 A	20-02-90
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